BLOODBORNE PATHOGEN SAFETY & HEALTH INSPECTION PROGRAM (BSHIP) PROTOCOL

I. DOSH Internal Strategic Plan

In addition to the Five Year Strategic Plan submitted to Federal OSHA, the Division shall maintain the Bloodborne Safety and Health Inspection Program (BSHIP) as an internal strategic plan addition.

II. BSHIP: A 2003 Performance Goal

A. BSHIP Prevention Challenges To Be Met

The Bloodborne Pathogens Safety and Health Inspection Project supports Strategic Goal One of the Division's Five-Year Strategic Plan, i.e., improving workplace safety and health as evidenced by fewer hazards, reduced exposures and fewer injuries and illnesses.

The challenge that the BSHIP will address is reduction in the risk of exposure to bloodborne pathogens (BBP) among affected workers through focused enforcement and consultative activities.

Blood and other potentially infectious materials have long been recognized as a potential threat to the health of workers who are exposed to these materials by percutaneous (and other types of) contact. Injuries from contaminated needles, and other sharps, have been associated with an increased risk of disease from more than twenty bloodborne infectious agents.¹

The Centers for Disease Control and Prevention has estimated that healthcare workers in U.S. hospital settings sustain 385,325 percutaneous injuries involving contaminated sharps annually. When non-hospital workers are included, the estimate of the number of percutaneous injuries involving contaminated sharps is 590,164 per year. Such injuries can lead to serious or fatal infections with BBPs, such as the human immunodeficiency virus (HIV), hepatitis B virus (HBV) or the hepatitis C virus (HCV). Beginning in July of 1998 in California with amendments to 8 CCR 5193 (mandated by Labor Code Section 147.7), and extending to the federal Needlestick Safety and Prevention Act of 2000, various state and federal laws and regulations have been enacted to reduce needlestick injuries among healthcare workers.

¹ Examples of bloodborne pathogens include: human immunodeficiency virus (HIV); hepatitis B virus (HBV); hepatitis c virus (HCV); syphilis, malaria, brucellosis, leptospirosis, arboviral infections (Colorado Tick Fever); relapsing fever; Creutzfeldt-Jakob disease; human T-lymphotropic virus Type I; and viral hemorrhagic fever (Laesa, Marburg, Ebola and Crimean-Congo hemorrhagic fever).

B. Enforcement and Consultative Tools

The programmatic tools that the BSHIP will use are enforcement and consultative tools. Specifically, the BSHIP will assist California employers in complying with California's Bloodborne Pathogens Standard (8 CCR 5193) through telephonic and on-site consultative assistance, and will assess, through enforcement investigations (programmed and unprogrammed), compliance with 5193 among employers in Major SIC Code 80 (SIC Codes 8011 through 8099).

C. Management and Coordination

The BSHIP Overall Activities Managers will be Vicky Heza, Deputy Chief for Cal/OSHA Enforcement and Steven C. Smith, Supervising Industrial Hygienist.

Northern California Enforcement Activities Coordinator (including HHU North) will be Amalia Neidhardt, Region II Senior Industrial Hygienist. Southern California Enforcement Activities Coordinator (including HHU South) will be Peter Riley, Anaheim High Hazard Unit District Manager.

The Consultation Services' Activities Coordinator will be Richard DaRosa, Senior Industrial Hygienist in the Consultation Services' Technical Support Unit.

The BSHIP Technical Advisers will be Deborah Gold, Bob Barish and Bob Nakamura, Senior Industrial Hygienists in the Research and Standards Health Unit.

Education Adviser will be Jack Oudiz, Professional Development and Training Unit Coordinator, and the BSHIP Legal Adviser will be Len Welsh, Special Counsel for Regulatory Affairs.

The BSHIP Medical Advisers will be Larry Rose, M.D., Tam Smalstig, R.N. and Mary Kochie, R.N..

D. Timeline

The Bloodborne Pathogens Safety and Health Inspection Project started in FY 2002 as a strategic plan item and will be continued in FY 2003 onward as an Internal Performance Plan Goal.

III. BSHIP Focus

BSHIP will provide consultative assistance to, and conduct enforcement inspections of, establishments whose activities involve occupational exposure, e.g., establishments in Major SIC Group 80, even though the scope of establishments covered by 8 CCR 5193 is larger than those found in Major Code 80 (SIC Codes 8011 through and including 8099).

IV. BSHIP Consultative Assistance

A. Educational Outreach

BSHIP educational outreach will occur through contacts made by the Cal/OSHA Consultation Service and by the Cal/OSHA Enforcement Unit with California healthcare facility associations, including acute and chronic care facility associations, clinical laboratory associations, outpatient clinic and other healthcare facility associations, California healthcare workers' unions, and California community groups concerned with prevention of bloodborne pathogens exposure in the workplace.

B. Establishment Selection

1. Requested Consultation Assistance

One of the major ways that establishments are selected for consultative assistance is through self-selection. Through educational outreach, and as a result of increased BSHIP enforcement activity, it is possible that there will be an increase in requests for consultative assistance by employers in Major SIC Code 80.

Requests for telephonic and on-site assistance from employers in Major SIC Code Group 80, who otherwise meet consultative criteria for assistance, will be prioritized by Consultation Service Area Offices to receive assistance from a BSHIP trained Industrial Hygienist.

2. High Hazard Consultative Assistance

All establishments on the List of Employers for High Hazard Consultation, i.e., those establishments with experience modification ratings (ExMODs) of 125% or greater, which fall into Major SIC Code Group 80, will be identified by the High Hazard Consultation Coordinator. These establishments will be assigned to an Area Office consultant for high hazard consultative assistance during the BSHIP.

C. Consultative Assistance Procedures

When conducting an on-site assistance visit, consultants shall follow established consultation field procedures.

D. Technical and Medical Assistance

Technical Assistance

The Senior Industrial Hygienists in the Consultation Services' Technical Support Unit and in the Research and Standards Health Unit are able to assist consultants when issues of a technical or regulatory nature arise.

Richard DaRosa (916) 263-5759 Bill Obert (619) 767-2060 Deborah Gold (415) 703-5115 Bob Barish (415) 703-5161 Bob Nakamura (415) 703-5160

Medical Assistance

At any time in the course of a consultative assistance on-site visit, consultants may contact the Medical Unit for assistance with the medical aspects of the Bloodborne Pathogens Standard, especially violations of 5193(f), pertaining to Hepatitis B Vaccination and Post-Exposure and Follow-Up.

Larry Rose, M.D. (415) 703-5159
Tam Smalstig, R.N. (714) 456-1876
Mary Kochie, R.N. (818) 901-5751
Janice Prudhomme, D.O, M.P.H. (510) 622-4323

E. Collection and Reporting of Activity and Outcome Measures

Consultants will code telephonic and on-site consultations provided to establishments in Major SIC Code 80 for activity and outcome measurement. See Section VII. The Consultation Services' BSHIP Coordinator will be responsible for ensuring that all required BSHIP activity and outcome measures are collected and reported to the BSHIP Managers at appropriate intervals.

V. BSHIP Enforcement

A. Establishment Selection

1. Unprogrammed Inspections

An establishment that is selected for an unprogrammed inspection is selected by the complainant.

All unprogrammed inspections (i.e., formal complaints and non-formal complaints which either allege a needlestick injury or another type of violation which can be characterized, from information provided by the complainant, as serious by the District Manager) triggered by a complaint referencing a bloodborne pathogens issue in an establishment in Major SIC Code 80 shall be assigned to an industrial hygienist. Each of these investigations shall be tracked as a BSHIP investigation, and activity and outcome measures collected and recorded for each unprogrammed investigation. See Section VII.

2. Programmed Inspections

The Division believes that such programmed inspections of establishments in Major SIC Code 80 is necessary to ensure

that employers are complying with 8 CCR 5193 (adopted in July of 1999 by the Occupational Safety and Health Standards Board).

Major SIC Code 80 establishments will be randomly selected for a BSHIP programmed inspection. Establishments for a BSHIP programmed inspection will be randomly selected to maximize the application of enforcement resources, i.e., where non-compliance with 5193 may be greater, where the risk of exposure to bloodborne pathogens may be greater, and where large numbers of workers are potentially at-risk in any one establishment.

B. Investigation Procedures

1. BSHIP Industrial Hygienists

All unprogrammed and programmed BSHIP investigations shall be conducted by an industrial hygienist who has received training given by the Division in how to enforce the amended bloodborne pathogens standard. Approximately 25 enforcement industrial hygienists were trained in FY 2002 in the BSHIP protocols, and additional industrial hygienists will be trained in FY 2003 and beyond as needed. This training gives the BSHIP-participating industrial hygienist the tools he or she requires to effectively collect the BSHIP outcome measures during an investigation.

2. BSHIP Procedures

a. General Procedures

See the Division's Policy and Procedures Manual, especially P&P Section C-14 which sets forth detailed procedures for the enforcement of 8 CCR 5193.

b. Specific BSHIP Procedures

Outcome measure data-gathering tools will be available for enforcement and consultative personnel to utilize during a BSHIP investigation or consultation to ensure the accurate collection of outcome measures. An Outcome Measures form shall be filled out for each BSHIP inspection and submitted to the BSHIP Coordinator and the Deputy Chief.

A non-mandatory Device Checklist maybe used to assist in determining compliance with the ESIP requirements for all sharps. Any Device Checklist forms filled out shall be submitted to the BSHIP Coordinator who shall provide a copy to the R&S Health Unit for potential research purposes.

C. Technical and Medical Assistance

Technical Assistance

Senior Industrial Hygienists in the Division's Research and Standards Health Unit are available to assist enforcement industrial hygienists when issues of a technical or regulatory nature arise.

Deborah Gold (415) 703-5115 Bob Barish (415) 703-5161 Bob Nakamura (415) 703-5160

Medical Assistance

At any time during the course of a bloodborne pathogens investigation, enforcement personnel are encouraged to contact the Medical Unit for assistance in collecting evidence to sustain alleged violations of 5193, especially violations of 5193(f), pertaining to Hepatitis B Vaccination and Post-Exposure and Follow-Up.

There are several ways that the Medical Unit can assist enforcement personnel when they conduct an investigation involving 5193, e.g., assistance through telephonic contact, review of medical records, on-site assistance (when appropriate) to conduct interviews with evaluating healthcare professionals.

Larry Rose, M.D. (415) 703-5159
Janice Prudhomme, D.O., M.P.H. (510) 622-4323
Tam Smalstig, R.N. (714) 456-1876
Mary Kochie, R.N. (818) 901-5751

D. Collection and Reporting of Activity and Outcome Measures Enforcement personnel will code investigations of establishments in Major Group 80 for activity and outcome measurement. See Section VII.

The Northern and Southern California BSHIP Enforcement Coordinators will be responsible for ensuring that all required BSHIP activity and outcome measures are collected during each BSHIP investigation.

E. Citation Review. The District Manager shall review all BSHIP citations for consistency with enforcement policy. The District Manager may consult with the Enforcement Activities Coordinator

prior to issuance of citations.

VI. BSHIP Training

Bloodborne Pathogens Training Courses were conducted for Division industrial hygienists in 2000. BSHIP specific training was conducted in 2001 and 2002. Additional BSHIP-specific training will be scheduled as needed annually through the Division's Professional Development and Training Unit in coordination with the BSHIP Consultation and Enforcement Activities Coordinators and Technical Advisors.

VII. Collection and Reporting of Activity & Outcome Goals and Measures

A Activity Goals and Measures

A large number of activity measures are routinely collected and reported during the course of any on-site consultation or enforcement investigation, e.g., number of on-site consultations or enforcement investigations conducted by SIC Code, number and type of violation of 5193 noted or cited, time employer abates the violative condition, and other measures of consultative or enforcement activity.

BSHIP will make use of these standard activity measures to assess whether BSHIP has met its Activity Goals.

- 1. Consultation BSHIP Activity Goals and Measures
 - a. Assistance Activity Goal and Measure The number of telephonic and on-site assistance visits to employers in Major SIC Code 80 which are rendered by each Area Office will be collected and reported.
 - b. Publication Dissemination Activity Goal and Measure
 Consultation has two major publications on the topic
 of bloodborne pathogens: "Exposure Control Plan for
 Bloodborne Pathogens" and "A Best Practices
 Approach for Reducing Bloodborne Pathogens
 Exposure." Dissemination of these two publications
 to interested employers in Major SIC Code 80 is
 expected to increase compliance with 5193.

The number of BBP publications which are provided to employers in Major SIC Code 80 by the Consultation Service will be collected and reported by the Education Unit to the Consultation Services' BSHIP Activities Coordinator. The BSHIP Activity Goal for BBP Publication Dissemination is 5,000

publications per year.

 BBP Outreach Presentation Activity Goal and Measure

The number of BBP presentations which are provided to employers in Major SIC Code 80 by each Area Office of the Consultation Service will be collected and reported by the Consultation Services' BSHIP Activities Coordinator. The BSHIP Activity Goal for BBP Presentations is 20 presentations per year.

Enforcement BSHIP Activity Goals and Measures

Prior to BSHIP, the Division has not conducted programmed enforcement investigations in most establishment subgroups in Major SIC Code 80 Each BBP investigation will be coded in IMIS and information about the number of investigations conducted by each District Office, as well as the violations cited in each investigation and other activity measures, will be collected and reported by reference to Strategic Plan Codes in IMIS (See IMIS Data Entry for the Cal/OSHA 1).

B. Consultation and Enforcement Outcome Goals and Measures
BSHIP Outcome Goals are designed to assess both the
compliance of the establishment with the two most recently added
risk-reduction provisions of the 1999 Bloodborne Pathogens
Standard, i.e., Exposure Response, Prevention and Control
(5193(c)) and Engineering and Work Practice Controls (5193(d)(3)),
but are also designed to assess outcomes beyond these
intermediate risk-reduction outcome goals, infection prevention
goals, e.g., HBV vaccination rates among affected workers, and
injury and disease incidence reduction goals.

Due to the difficulties in measuring ultimate outcome measures like injury and disease incidence in small samples like BSHIP, BSHIP will emphasize the collection and reporting of intermediate administrative (regulatory compliance) outcome measures, and infection prevention outcome measures, at the time of the initial consultation and enforcement investigation, and at a follow-up point of time² to assess the efficacy of the consultation or enforcement investigation.

- 1. Injury Prevention Outcomes
 - a. Exposure Control Plan
 - (1) Have the employer's written ECP procedures

² Follow-up evaluation can occur at the time violative conditions are set for abatement, or another point of time subsequent to the initial consultation or enforcement investigation. Follow-up evaluation of outcomes can occur on-site or from a telephonic or mailed survey instrument.

been updated to reflect current 5193(c)(1)(B) requirements

- (2) Has the employer obtained the active involvement of non-managerial employees in:
 - a. Reviewing and updating the ECP?
 - b. Selecting devices with ESIP?
- (2) Can the employee describe what type of postexposure evaluation and follow-up the employer is required to provide in case of an exposure incident?

b. Sharps Injury Log Requirements

For each exposure incident from a sharp without ESIP recorded in the Sharps Injury Log, has the employer solicited and recorded the employee's opinion:

- (1) About whether and how such a mechanism could have prevented the injury?
- (2) About whether any engineering, administrative or work practice controls could have prevented the injury?
- c. Engineering Controls
 - (1) Are ESIP devices in use at the employer's establishment?
 - (2) What types of devices with ESIP are in use in the employer's establishment? See non-mandatory Device checklist for assistance and suggestions in evaluating ESIP use.
- d. Training Effectiveness
 - (1) Does the employer provide effective training about:
 - a. Exposure Incidents
 - i. Can the employee describe what to do in the event of an exposure incident?
 - ii. Can the employee describe who to report the incident to?
 - b. Universal Precautions

Can the employee describe the practice of universal precautions?

c. ESIP Device Use

Did the employee receive training on the use of the ESIP device?

- 2. Infection Prevention Outcome HBV Vaccination
 - (A) What is the proportion of employees with occupational exposure at the employer's establishment that have been vaccinated for HBV?
 - (B) What is the proportion of employees not HBV-vaccinated for whom the employer has a signed declination statement on file?
- Sharps Injury Incidence Reduction Outcome

During the course of each initial BSHIP consultation and enforcement investigation, an accurate assessment will be made of the number of exposure incidents that are recorded (or should have been recorded) on the establishment's Sharp Injury Log. The initial number of exposure incidents will be compared to the number recorded at a follow-up point in time after the initial consultation or enforcement investigation.

The outcome goal is to reduce by 3% annually the number of needlestick injuries (as measured by employers' Sharps Injury Log Data) for each BSHIP establishment.

4. Sharps Injury Associated Disease Reduction Outcome

Due to the low incidence rate of sharps injury associated disease outcomes, even in a large sample of workers, the effect of a limited program of consultative visits and enforcement investigation on the overall disease incidence rate is likely to be difficult to reliably measure.

BSHIP will, however, endeavor to assess on an annualized basis the number of disease outcomes attributed to sharps injuries and reduce the incidence rate by 3% annually (as measured by relevant state and national disease databases).

VIII. Legal Issues

P&P C-14, Section F., sets forth procedures relating to the Division's Citation Policy for enforcement of 8 CCR 5193. It is important to remember that violations of 8 CCR 5193 that are classified as "Serious" merit legal scrutiny when contested by the employer.

Regarding the issue of what constitutes "substantial probability of death or serious physical harm" see Labor Code Section 6432 and 8 CCR Section 336. When any BSHIP citation alleging a serious violation of 5193 is contested by the employer, the BSHIP Enforcement Coordinators shall ensure that district managers consult with the Legal Unit to determine if legal representation is necessary.

BSHIP Outcome Measures Report

Inspection Number				Inspection Date					
CSHO				Region					
N	ame	of E	stablishment _						
Si	c Co	ode:			ent				
							Yes	No	
1.	In	jury P	revention Outco	mes			165	110	
	a. Exposure Control Pla								
		1.	Is the ECP upda (5193(c)(1)(B) ²	ated to include new 5193 4 to 8)	S(c)(1)(B) requirem	nents?			
		2a.		erial ee's involved in revi	ewing/updating EC	CP? (5193(c)(1)(B)8.)			
		2b.	Are non-manag (5193(c)(1)(E))	erial ee's involved in sele	ecting devices with	ESIP?			
		3.	Does the plan of	lescribe post-exposure ev		w up including			
	b.	Sha	rps injury log	alternate provider? (519	33(C)(1)(B)2.)				
	U.	1.	For each expos	ure injury w/o ESIP, does		e opinion re whether			
		2.		re prevented the injury? (ontain ee opinion re whet		ng, administrative or			
				ontrol would have prever					
	c.	Are		devices in use at this est	-				
			• •		no ESIP devices None applicable				
		Ш	applicable ESI		establishment	TOI CHIS			
	d.	Trai 1.		oyee interviews) describe what to do if th	oro's an eynosure	incident?			
		1.	(5193(g)(2)(G)	11.)	·				
		2.	(5193(g)(2)(G)						
		3.	Can employees	explain universal precau	tions? (5193(g)(2)	(G)6.)			
		4.		ees receive training on thor 5193(g)(2)(G)6.)	ne ESIP devices the	ey use?			
2.				HBV vaccination (To be te: a = b+c+d+e)	used for establish	ments or units with			
	a.		-	employees have occupation					
	b.		how many OE e 93(h)(1)(B)2.)	mployees in 2(a) is there	e an up-to-date vac	ccination record?			
	c.	For	how many OE e	mployees in 2(a) is there		tion of up-to-date			
	d.		` •	nployee written statemen oyees in 2(a) have no or	•	nentation, or			
		documentation that shows they're not up-to-date? (5193(f)(2))							
	e.		v many OE empi 93(f)(2)(D))	byees in 2(a) have signed	a tne requirea aeci	lination?			
3.			any sharps injurio 3 full calendar y	es has the employer reco rears	orded for the curre	nt year <i>to date</i> and in			
			2003	2002	2001	2000			
4.	Cit	ations	s#	5193 Serious	# 5193 other th	an serious	# other th	an 5193	

BSHIP Device Checklist

Fa	cility							
Ins	spection #CSHO							
1.	Needles and Syringes or other Injection systems for Medication Delivery (Not applicable to this facility)							
	1. Facility uses conventional syringes for medication delivery:							
	Unit Procedure Medication Brand Size gauge							
	Brand Cat #size gauge							
	Needle length Reason							
П	2. Hinged recap: a. Needle Pro (Sims Portex)b. Other							
	3 Needleless: a Riofree h Equidyne c Other							
	3. Needleless: a. Biofree b. Equidyne c. Other 4. Retractable: a. Vanish Point b. NMT c. Other							
_	5. Sliding Sheath: a. Safety Glide (BD)b. Safety Lok (BD)c. Monoject							
<u> </u>	6. Other							
2	Pre-filled Syringes without ESIP (Not Applicable to this facility)							
۷.	Unit Procedure Medication Dose							
	Unit Procedure Medication Dose							
	Needle length Special consideration?							
	Reason							
	Is medication available for administration through ESIP devices?							
	1. Add-on device used: BrandCat #							
	sizeGauge							
	2. Add-on is assembled at point of use							
	3. Add-on and syringe are pre-assembled.							
	4. Prefilled syringe has leur hub and is used without needle for administering							
	medication into a line							
	5. Other							
3.	Lancets (Not applicable to this facility)							
	1. Facility uses conventional lancets							
	Unit Procedure Brand							
	Cat # Type Gauge							
	Reason							
	2. Accu-Chek Safe-T-Pro (Roche Diagnostics)							
	3. EZ Lets II single use, disposable finger lancing device (Palco Labs)							
	4. Gentle-let1 (Lukens Medical)							
	5. Glucolet 2 with Fingerstix lancets/end cap (Miles/Bayer)							
	6. Haemolance Lancets Haemedic AB							
	7. Microtainer Brand, Genie or Microtainer Brand Quikheel Lancet (BD)							
	8. Monolettor lancet (Kendall/Sherwood)							
	9. Single-Let (Bayer)							
	10. SurgiLance Capillary blood sampling device (Futuro Medical)							
	11. Unistik 1 or Unitstik 2 (Owen Mumford)							
	Other							

Send a copy of completed form with the Outcome Measures Report to your BSHIP Coordinator